(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 December 2001 (27.12.2001)

PCT

(10) International Publication Number
WO 01/97677 A2

(51) International Patent Classification[7]: A61B

(21) International Application Number: PCT/US01/19653

(22) International Filing Date: 20 June 2001 (20.06.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/213,263 22 June 2000 (22.06.2000) US

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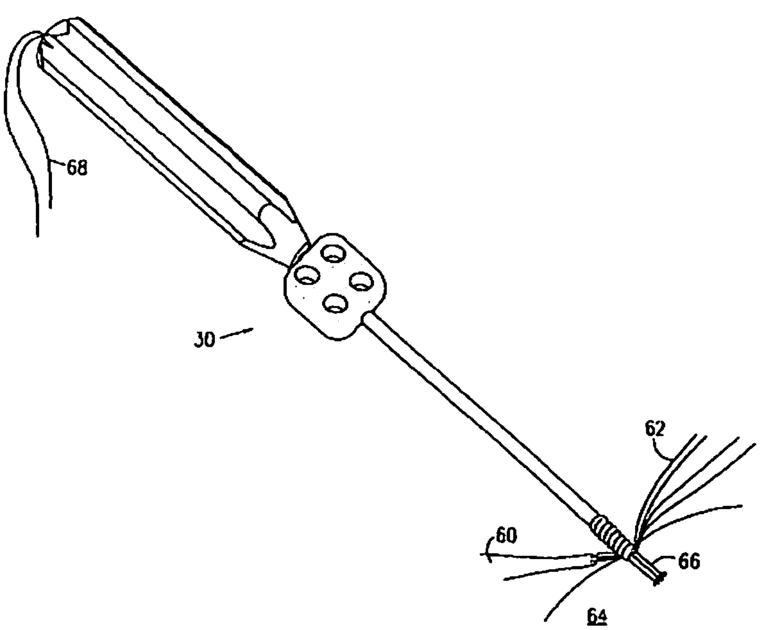
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European

[Continued on next page]

(54) Title: GRAFT FIXATION USING A SCREW OR PLUG AGAINST SUTURE OR TISSUE



(57) Abstract: A method for securing soft tissue to bone with excellent pull-out strength which does not require the surgeon to tie suture knots to secure the tissue to the bone. A blind hole or socket is created in the bone at the location the graft is to be secured. Preferably, suture is then passed through the graft at desired points. A cannulated driver is pre-loaded with a cannulated plug or screw slidably disposed onto the distal portion of the driver. In a preferred embodiment, a separate piece of suture is passed through the cannula of the driver with a loop end of that suture exposed at the distal end of the driver. The ends of the suture attached to the graft are fed through the suture loop at the end of the driver. Alternatively, the graft itself may be fed through the suture loop, in which case it is not necessary to attach suture through the graft. In another embodiment, the suture loop exposed at the distal end of the cannula of the driver may be omitted, and the sutures attached to the graft may then be fed through the driver cannula from the distal end to position the graft relative to the driver. The driver is inserted into the hole with the screw or plug just outside the hole. Tension is then placed on the suture. Once adequate tension is achieved on the suture, the driver is pressed into the hole, which engages the first thread or bump of the screw or plug on the bone. The screw or plug is then fully advanced into the hole using the driver. When the screw or plug is fully inserted, the suture loop is freed and the driver is removed. The loose ends of the sutures protruding from the anchor site can be cleaned up by clipping them short.

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patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report*

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GRAFT FIXATION USING A SCREW OR PLUG AGAINST SUTURE OR TISSUE

BACKGROUND OF THE INVENTION

1. Field of the Invention:

The present invention relates to methods and apparatus for fixation of sutures and soft tissue to bone using a screw or plug.

2. Description of the Related Art:

When soft tissue such as a ligament or a tendon becomes detached from a bone, surgery is usually required to reattach or reconstruct the tissue. Often, a tissue graft is attached to the bone to facilitate regrowth and permanent attachment. Various fixation devices, including sutures, screws, staples, wedges, and plugs have been used in the past to secure soft tissue to bone. In typical interference screw fixation, for example, the graft is fixed to the bone by driving the screw into a blind hole or a tunnel in the bone while trapping the end of the graft between the screw and the bone tunnel. In other methods, the graft is simply pinned against the bone using staples or sutures tied around the end of the graft to the bone.

More recently, various types of threaded suture anchors have been developed. The application of such suture anchors generally requires the surgeon to tie knots in the suture to secure the tissue to the bone, which is tedious and time-consuming. The surgical procedure would be less cumbersome for the surgeon and ultimately more beneficial to the patient if the tissue could be attached to the bone without the surgeon having to tie suture knots.

SUMMARY OF THE INVENTION

The present invention provides a surgical technique and associated device for securing soft tissue to bone with excellent pull-out strength and which does not require the surgeon to tie suture knots to secure the tissue to the bone. The

present invention may be used to secure any type of soft tissue, graft, or tendon, such as, for example, a biceps tendon or a rotator cuff.

In a preferred embodiment of the invention, a blind hole or socket is created in the bone at the location that the graft is to be secured. Suture is passed through the graft at desired points. A cannulated plug or screw is pre-loaded onto the distal end of a cannulated driver. In a preferred embodiment, a separate piece of suture is passed through the cannula of the driver, with a looped end of the suture exposed at the distal end of the driver. The ends of the suture attached to the graft are fed through the suture loop at the end of the driver. The distal end of the driver is inserted into the bottom of the hole, with the screw or plug disposed just outside the hole. Tension is then placed on the suture(s) to position and hold the graft at an appropriate distance relative to the distal end of the driver. Once adequate tension is achieved on the suture, the driver is pressed into the hole, engaging the first thread or bump of the screw or plug. The screw or plug is then fully advanced into the hole using the driver. When the screw or plug is fully inserted, the suture loop is freed and the driver is removed. The loose ends of the sutures protruding from the anchor site are then clipped short.

Alternatively, the step of passing suture through the graft may be omitted, so that the graft itself is captured in the suture loop to be directly affixed into the fixation hole.

In another alternative, the suture loop through the driver may be omitted, and the graft is positioned relative to the driver by inserting the ends of the suture attached to the graft into and through the cannula of the driver from the distal end thereof.

Other features and advantages of the present invention will become apparent from the following description of the invention which refers to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates a proximal end, side elevational view of an embodiment of an interference screw to be used with the present invention.

Fig. 2 is a proximal end view of the screw shown in Fig. 1.

Fig. 3 is a cross-sectional view, drawn along line III-III of Fig. 2, of the screw shown in Fig. 1.

Fig. 4 illustrates a side elevational view of an embodiment of an interference plug according to the present invention.

Fig. 5 is a cross-sectional view of the plug shown in Fig. 4.

Fig. 6 is a distal end view of the plug shown in Fig. 6.

Fig. 7 illustrates a driver according to the present invention for driving the interference screw shown in Fig. 1.

Fig. 8 shows a handle according to a variation of the driver seen in Fig. 7.

Fig. 9 shows the inner shaft attachable to the driver handle shown in Fig. 8.

Fig. 10 shows the outer shaft of the driver according to the present invention.

Fig. 11 illustrates an alternative embodiment of a driver for driving an interference screw, together with a screw loaded thereon.

Figs. 12A and 12A illustrate a driver according to the present invention usable for the interference plug shown in Fig. 4.

Fig. 13 illustrates a punch usable in connection with the present invention to create a bone socket for securing the graft.

Fig. 14 illustrates a graft to be secured to the bone with attached sutures, and a socket created in the bone at the location at which the graft is to be affixed.

Fig. 15 shows the driver of Fig. 7 loaded with an interference screw and having a traction suture loop formed at the distal end of the driver.

Fig. 16 illustrates the sutures attached to the graft being passed through the suture loop according to the present invention.

Fig. 17 is a view through a cross-section of the bone socket which shows the sutures attached to the graft being held in contact with the bottom of the bone socket with the interference screw positioned just out of the socket.

Fig. 18A is a view through a cross-section of the bone through the socket.

Fig. 18B illustrates the same step of the invention as shown in Fig. 18A, but provides a close-up view from the surgeon's perspective.

Fig. 19 shows the graft secured to the bone as a result of the method according to the present invention.

Fig. 20 illustrates an alternative embodiment of the method according to the present invention in which the sutures attached to the graft are threaded directly into and through the driver instead of through a suture loop at the distal end of the driver.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Figs. 1-3, an interference screw **10** according to the present invention is shown. Screw **10** is preferably formed of a bioabsorbable material such as PLLA and has a cannulated body **12** provided with a continuous thread **16** having rounded outer edges **18**. The head of the screw **14** is rounded to minimize abrasion or cutting of tissue, and the screw tapers toward the distal end. A hexagonal bore **15** formed through the screw accepts a driver shaft described in more detail below.

Figs. 4-6 illustrate an interference plug **20** according to an alternative embodiment of the present invention. Plug **20** is also preferably formed of a bioabsorbable material and has a cannulated body **22** provided with rounded annular ribs **24** separated by rounded annular grooves **26**. The outer diameter of the ribs and grooves is substantially constant. The plug tapers significantly toward the distal end. Cannula **28** is preferably round in cross-section but may also be hexagonal or any other shape, and is designed to accommodate the shaft of a corresponding driver.

Fig. 7 illustrates a driver **30** according to the present invention for driving the interference screw described above. Generally, driver **30** includes a handle **32**, inner shaft **34**, and outer shaft **36**. Fig. 8 shows a handle having a connector **31** for coupling with driver **30**.

Fig. 9 shows the inner shaft of driver **30**. Inner shaft **34** has a cannula extending through its entire length and has openings at the proximal and distal ends to enable sutures to be passed therethrough. Inner shaft **34** includes a shaft body **38** having a threaded proximal section **39** and a hex-shaped distal section **35** for being fitted through the cannula **15** in interference screw **10**. The diameter of the shaft body **38** is reduced slightly along the hex section **35**, forming a shoulder **37** at the junction between the hex section **35** and the central portion of shaft body **38** for abutting the proximal end of an interference screw loaded onto the driver. Shaft **34** can be permanently affixed to the handle **32** as shown in Fig. 7, or can be releasably attached, as shown in the embodiment represented in Figs. 8 and 9, by means of a collet **33** at the proximal end of the threaded section **39** being fittable within a connector **31** at the distal end of handle **32**.

Fig. 10 shows the outer shaft **36** of the driver **30**. Outer shaft **36** includes a sleeve **40** which covers and is slidable over shaft body **38**, and a thumb pad **41** for being gripped by a user. Outer shaft **36** is cannulated through its entire length, of course, with the diameter of the cannula being slightly larger than the outer diameter of the central portion of inner shaft body **38**. The portion of the cannula through thumb pad **41** is threaded to mate with the threads on the threaded proximal section **39** on inner shaft **34**. The inner diameter of the inner threads in thumb pad **41** is smaller than the outer diameter of the central portion of shaft body **38**, so as to limit the proximal movement of the outer shaft **36** relative to the inner shaft **34**.

The proximal threaded section **39** on the inner shaft **34** has a length such that when the outer shaft **36** is unscrewed to its proximal-most position with the thumbpad adjacent the distal end of handle **32** or connector **31**, shoulder **37** on the inner shaft **34** is flush with or exposed through the distal end of sleeve **40** of outer shaft **36**.

The length of hex section **35** is such that when a cannulated interference screw is loaded onto the driver with the proximal end of the screw abutting the shoulder **37**, the hex driver portion exposed distally of the mounted screw can reach the bottom of a socket created in the bone where the screw will be inserted,

while the screw is positioned just outside the hole. Thus, the hex section **35** has a length which is approximately twice the length of the interference screw usable with the driver. Similarly, the length of the threaded proximal section **39** is also approximately equal to the length of the screw.

An alternative embodiment of the driver for the interference screw is shown in Fig. 11. In this embodiment, the outer shaft is eliminated so that the driver **30'** is comprised of a single cannulated shaft. The shaft body **38'** has an enlarged outer diameter relative to that of the previous embodiment, and tapers down to hex section **35'** via a tapered section **37'**. When loading a screw onto the driver **30'**, the proper initial position of the screw is established by inserting the hex section through the cannula of the screw until the travel of the proximal end of the screw **10** is limited by the increased diameter in tapered section **37'**. As before, the hex section has a length which enables the distal end of the hex section to be inserted to the bottom of the socket while positioning an intereference screw loaded onto the driver just outside the socket with the bottom thread of the screw able to engage the opening of the hole upon the application of a small amount of force into the hole.

Figs. 12A and 12B illustrate an example of a driver usable with an interference plug in accordance with the present invention, in which the plug is driven into the socket by impaction rather than being screwed into place. Driver **50** comprises essentially of an outer shaft **52** and a cannulated inner shaft **54**. Inner shaft **54** is inserted into the cannula **51** of outer shaft **52** and has a proximal portion **55** which has an outer diameter slightly smaller than the diameter of cannula **51** to enable the outer shaft **52** to slide along proximal portion **55**. Inner shaft **54** also has a distal portion **57** which has a diameter smaller than that of proximal portion **55** and sized for insertion into the cannula **28** of interference plug **20**. The cross-sectional shape of distal portion **57**, and hence of cannula **28** of plug **20**, is preferably round, but can also be hex or any other shape, as long as the distal portion **57** of inner shaft **54** is matingly shaped with the distal portion **57** of driver **50** to be insertable into cannula **28** of plug **20**. The junction between

proximal portion **55** and distal portion **57** forms shoulder **56** for abutting the proximal end of the plug when the plug is loaded onto the driver **50**.

The length of outer shaft **52** is equal to the length of proximal portion **55** of inner shaft **54** plus a distance "a" equal to the length of the interference plug usable therewith. The length of distal section **57** is approximately equal to twice the length of a plug **20**, and shoulder **56** on the inner shaft **54** is flush with or just exposed through the distal end of outer shaft **52** when outer shaft **52** is in its fully retracted (proximal) position.

A method of performing soft tissue fixation in accordance with a preferred embodiment of the present invention will now be described with reference to Figs. 14-19.

As shown in Fig. 14, sutures **62** are passed through the graft **60** at desired points, and a blind hole or socket **66** is created in the bone 64, using a drill or punch, at the location where the tissue is to be secured. A punch provides the advantages of rounding the opening edge of the bone socket to protect the sutures attached to the graft from being sheared during the insertion process, and also compacts the bone at the punch site for better purchase of the bone by the anchor in cases where the bone is a soft bone. An example of such a punch is illustrated in Fig. 13, the punch having a constant diameter section **72**, a tip **74**, a flared section **76**, and a main body portion **78**. The diameter of the constant diameter section corresponds to the diameter of the driver.

Next, as shown in Fig. 15, driver **30** is pre-loaded with screw **10** with outer shaft **36** in the fully retracted position and the distal end of the screw abutting shoulder **37** of inner shaft **34** and the distal end surface of outer shaft **36**. Traction suture **68** is passed into the cannula of the driver, such that a looped end **70** is exposed at the distal end of the driver. Sutures **62** attached to graft **60** are then passed through traction suture loop **70** at the end of driver **30** as seen in Fig. 16, to position the graft at an appropriate distance from the distal end of driver **30**, typically corresponding to the length of the screw.

Referring now to Fig. 17, the driver **30** is held with gentle pressure with the distal end of hex section **35** at the bottom of the hole **66**, keeping the screw **10**

just outside the hole. Tension can then be placed on the graft sutures **62** by drawing on traction suture **68** to tighten suture loop **70**. Once adequate tension is achieved on the sutures, the driver is manipulated so that the first thread edge of the screw engages the bone at the edge of the hole **66**. The driver is turned by rotating handle **32** and thus inner shaft **34** while preventing outer shaft **36** from rotating by holding thumb pad **41** in place during rotation of handle **32**. This maneuver causes the outer shaft to move distally along the inner shaft by the interaction of the inner threads in the outer shaft **62** with the threads on threaded portion **39** of inner shaft **34**, while also causing the screw threads to engage the sides of the hole and pull the screw into the hole. The inner shaft of the driver thus rotates without advancing further into the hole, while the outer shaft guides the insertion of the screw into the socket. In this manner, the screw advances along the hex section of the driver until the screw is fully installed to the position shown in Figs. 18A and 18B, with sutures **62** pinned and/or wound between the base and sidewall of socket **66** and interference screw **10**. Optionally, sutures **62** may be twisted together at the time they are passed through loop **70** to increase contact with the screw upon insertion of the screw into the socket.

After the screw is fully inserted, traction loop **70** is disengaged from the handle, and the driver is removed. As seen in Fig. 19, the ends of the sutures can be removed by clipping them short, leaving the graft securely fastened in place to the bone.

A procedure similar to that just described is performed with respect to the installation of an interference plug, except that a driver such as driver **50** shown in Figs. 12A and 12B is used instead of driver **30** of Figs. 7-10, and the plug is advanced into the hole using impact force supplied by a mallet, for example, rather than by turning. When the proximal end of outer shaft **52** is hit with the mallet, the proximal end of plug **20** abutting against shoulder **56** on the inner shaft **54** and the distal surface of outer shaft 52 pushes the plug into the socket **66**. In this method, the plug is fully inserted into the hole when the proximal end of outer shaft **52** is flush with the proximal end of inner shaft **54**.

In a first alternative to the method described above, sutures **62** attached to the graft **60** are eliminated, so that in the step shown in Fig. 16, the graft itself is passed through the suture loop **70** to be secured from the bottom of the hole **66** by the tip of plug **20**.

In a second alternative to the method described above, traction suture **68** and loop **70** are eliminated, so that in the step shown in Fig. 16, instead of passing sutures **62** through loop **70**, the ends of sutures **62** are threaded into the cannula of the inner shaft **34** through the distal end thereof, through the length of driver **30** or **50**, and out the opening at the proximal end thereof, as illustrated in Fig. 20.

A significant advantage provided by the method of the present invention is that the sutures attached to the graft or the graft itself can be securely attached to the bone without the need to tie knots.

Another advantage achieved by the present invention is that the sutures attached to the graft or the graft is secured both along the bottom of the bone socket by the tip of the interference screw or plug, as well as along the sidewall of the socket between the bone and the screw or plug. This arrangement results in a much stronger fixation of the graft to the bone than is achievable with prior art suture anchor procedures.

Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. Therefore, the present invention is to be limited not by the specific disclosure herein, but only by the appended claims.

WHAT IS CLAIMED IS:

1. A method of soft tissue repair, comprising the steps of:

forming a hole in a bone at a location at which a soft tissue graft is to be affixed;

attaching at least one suture to the soft tissue graft to be affixed;

capturing the suture attached to the graft and inserting the suture into the bottom of the hole;

drawing the soft tissue graft to the hole; and

installing a tissue anchor into the hole to secure the suture in the hole by interference-friction fixation between the tissue anchor and the bone forming the hole.

2. The method of graft repair according to claim 1, wherein the tissue anchor is a cannulated intereference device, and the method further comprises the steps of:

loading the cannulated interference device onto a cannulated driver; and using the driver to install the interference device into the hole.

3. The method of graft repair according to claim 2, wherein the interference device is a screw.

4. The method of graft repair according to claim 2, wherein the interference device is one of a wedge or a plug.

5. The method of graft repair according to claim 2, further comprising the step of passing suture through the cannula of the driver such that a loop of suture is exposed at the distal end of the driver, wherein the step of capturing the suture attached to the graft includes:

feeding the suture attached to the graft through the loop of suture at the distal end of the driver,

tightening the suture loop, and

inserting the distal end of the driver into the hole.

6. The method of graft repair according to claim 2, wherein the step of capturing and inserting the suture attached to the graft includes:

inserting the suture attached to the graft into the cannula of the driver from the distal end thereof,

feeding the suture through the driver to the proximal end thereof,

drawing the graft towards the distal end of the driver by pulling on the at least one suture from the proximal end of the driver, and

inserting the distal end of the driver into the hole.

7. The method of graft repair according to claim 2, wherein the driver includes an outer shaft disposed around an inner shaft and movable between a proximal position and a distal position along the inner shaft, and wherein the interference device is loaded onto the inner shaft by inserting the inner shaft through the cannula of the interference device with the outer shaft retracted to the proximal position so that the proximal end of the loaded interference device abuts the distal end of the outer shaft.

8. The method of graft repair according to claim 7, wherein

the interference device is a screw having a hex-shaped cannula,

a distal portion of the inner shaft of the driver is hex-shaped to be matingly insertable into the hex-chaped interference screw cannula,

the inner shaft of the driver is rotatable relative to the outer shaft to move the outer shaft between the proximal and distal positions therealong, and

the interference screw is installed by turning the inner shaft to drive the interference screw into the bone while preventing the outer shaft from rotating so that the outer shaft moves distally along the inner shaft to guide the interference screw into the bone.

9. The method of graft repair according to claim 7, wherein

the interference device is a plug,

the inner shaft of the driver is slidable relative to the outer shaft to move the outer shaft between the proximal and distal positions therealong, and

the interference plug is installed by impacting the outer shaft with a mallet until the proximal end of the outer shaft is aligned with the proximal end of the inner shaft, the interference plug being pushed into the bone by the distal end of the outer shaft.

10. A method of soft tissue repair, comprising the steps of:

forming a hole in a bone at a location at which a soft tissue graft is to be affixed;

capturing the soft tissue graft and inserting the soft tissue graft into the bottom of the hole; and

inserting a tissue anchor into the hole to secure the soft tissue graft in the hole by interference-friction fixation between the tissue anchor and the bone forming the hole.

11. The method of graft repair according to claim 10, wherein the tissue anchor is a cannulated interference device, and the method further comprises the steps of:

loading the cannulated interference device onto a cannulated driver;

passing suture through the cannula of the driver to expose a loop of suture at the distal end of the driver; and

using the driver to install the interference device into the hole,

wherein the step of capturing and inserting the graft includes:

feeding the graft through the loop of suture at the distal end of the driver,

tightening the suture loop from the proximal end of the driver, and

inserting the distal end of the driver into the hole.

12. The method of graft repair according to claim 11, wherein the interference device is a screw.

13. The method of graft repair according to claim 11, wherein the interference device is one of a wedge or a plug.

14. The method of graft repair according to claim 11, wherein the driver includes an outer shaft disposed around an inner shaft and movable between a proximal position and a distal position along the inner shaft, and wherein the interference device is loaded onto the inner shaft by inserting the inner shaft through the cannula of the interference device with the outer shaft retracted to the proximal position so that the proximal end of the loaded interference device abuts the distal end of the outer shaft.

15. The method of graft repair according to claim 14, wherein

the interference device is a screw having a hex-shaped cannula,

a distal portion of the inner shaft of the driver is hex-shaped to be matingly insertable into the hex-shaped interference screw cannula,

the inner shaft of the driver is rotatable relative to the outer shaft to move the outer shaft between the proximal and distal positions therealong, and

the interference screw is installed by turning the inner shaft to drive the interference screw into the bone while preventing the outer shaft from rotating so that the outer shaft moves distally along the inner shaft to guide the interference screw into the bone.

16. The method of graft repair according to claim 14, wherein

the interference device is a plug,

the inner shaft of the driver is slidable relative to the outer shaft to move the outer shaft between the proximal and distal positions therealong, and

the interference plug is installed by impacting the outer shaft with a mallet until the proximal end of the outer shaft is aligned with the proximal end

of the inner shaft, whereby the interference plug is pushed into the bone by the distal end of the outer shaft.

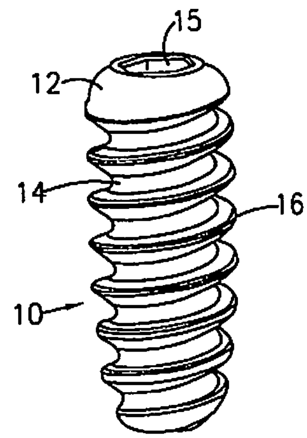

FIG. 1

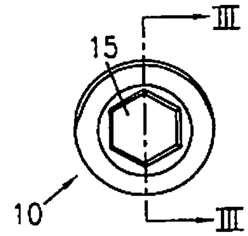

FIG. 2

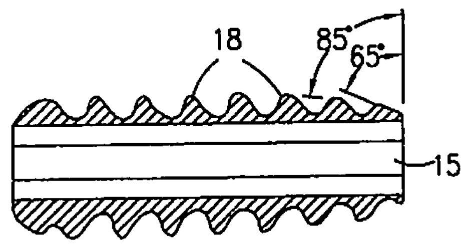

FIG. 3

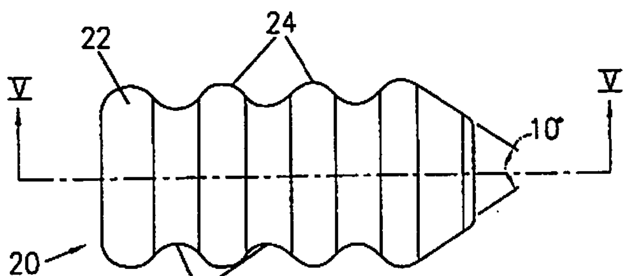

FIG. 4

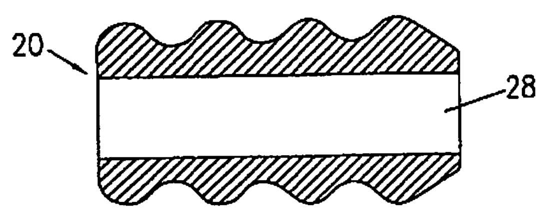

FIG. 5

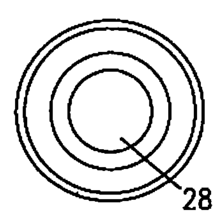

FIG. 6

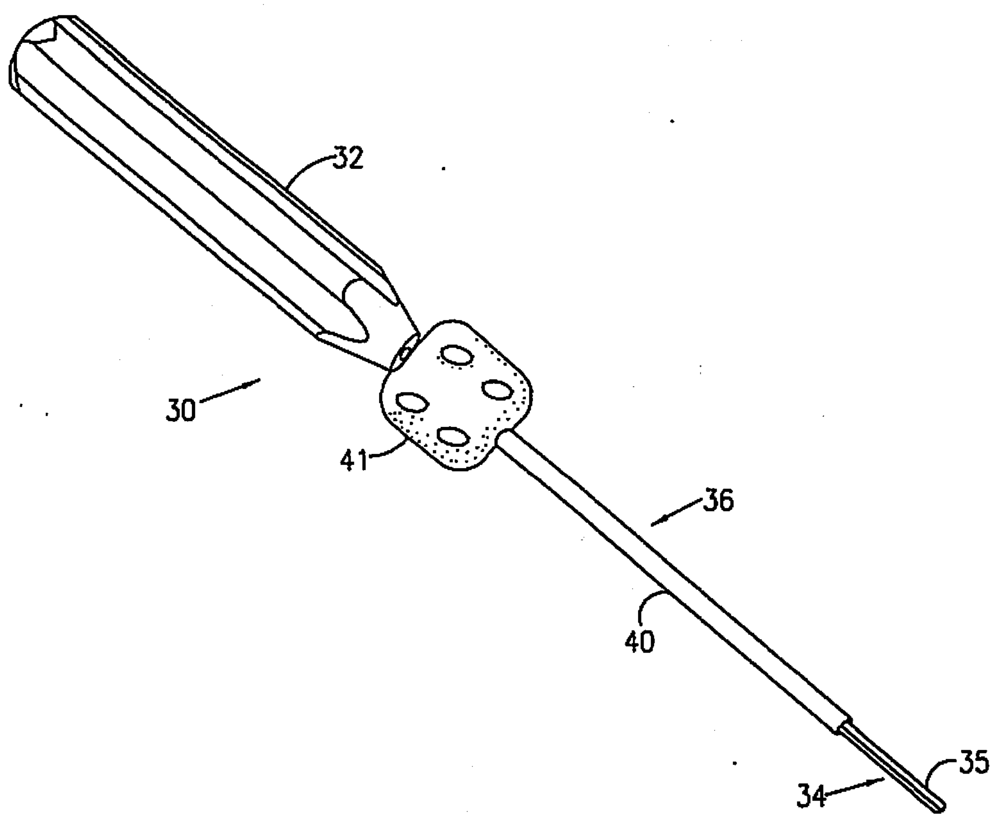

FIG. 7

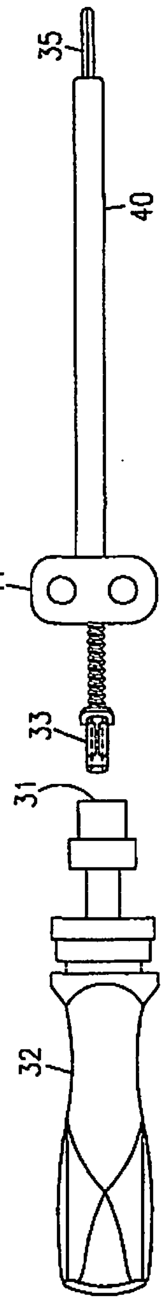

FIG. 8

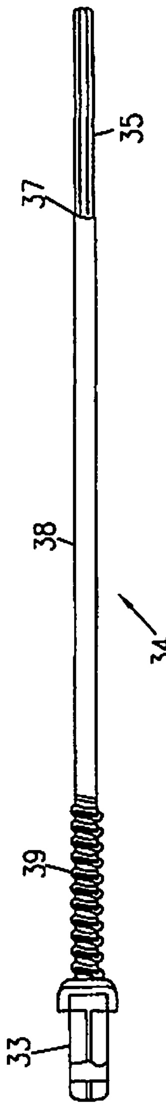

FIG. 9

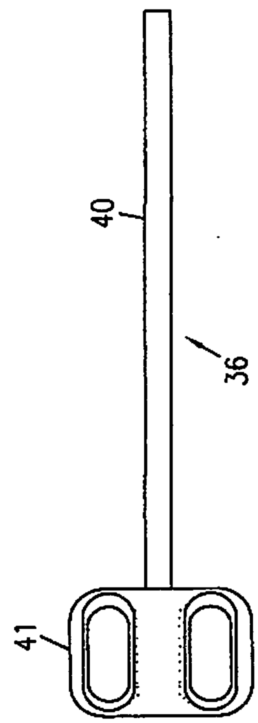

FIG. 10

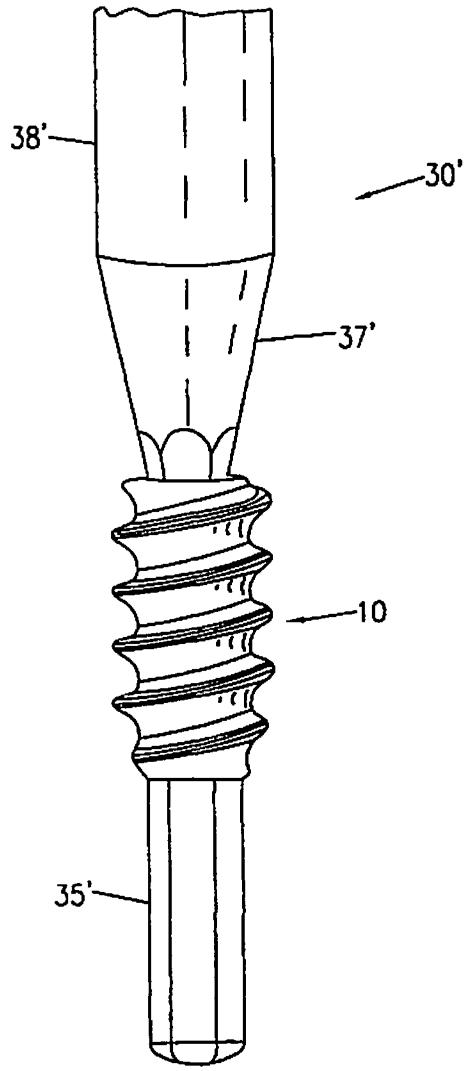

FIG. 11

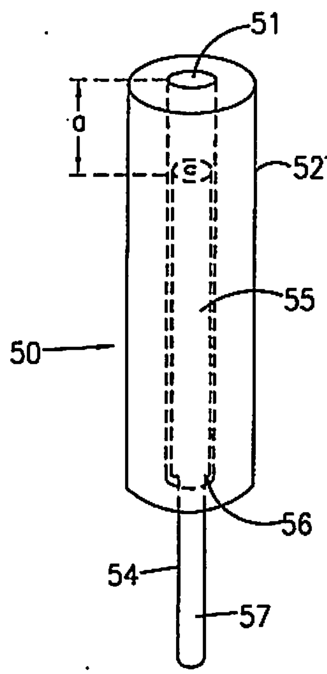

FIG. 12A

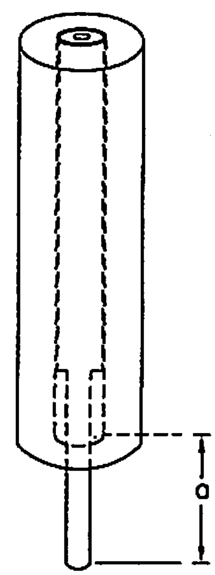

FIG. 12B

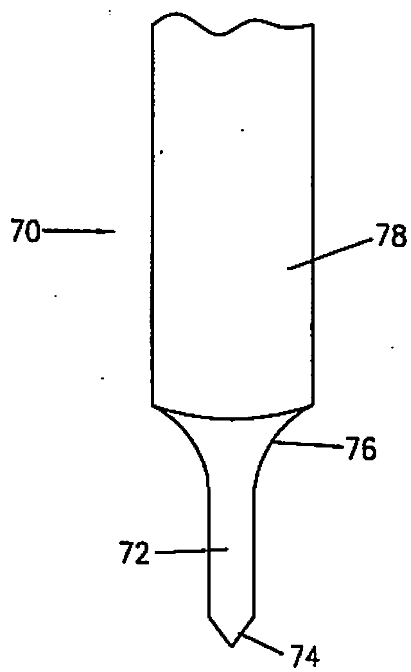

FIG. 13

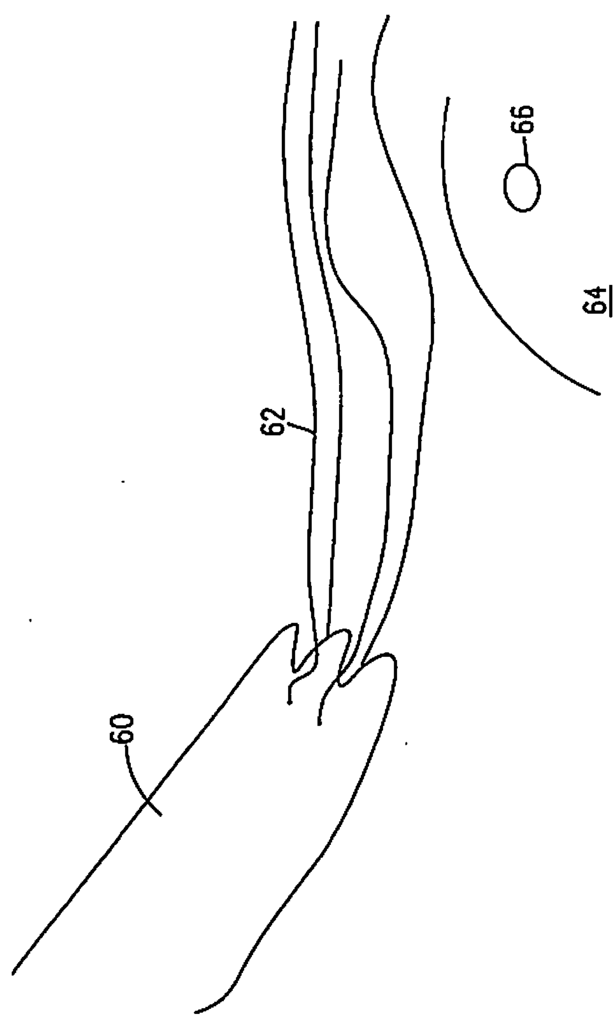

FIG. 14

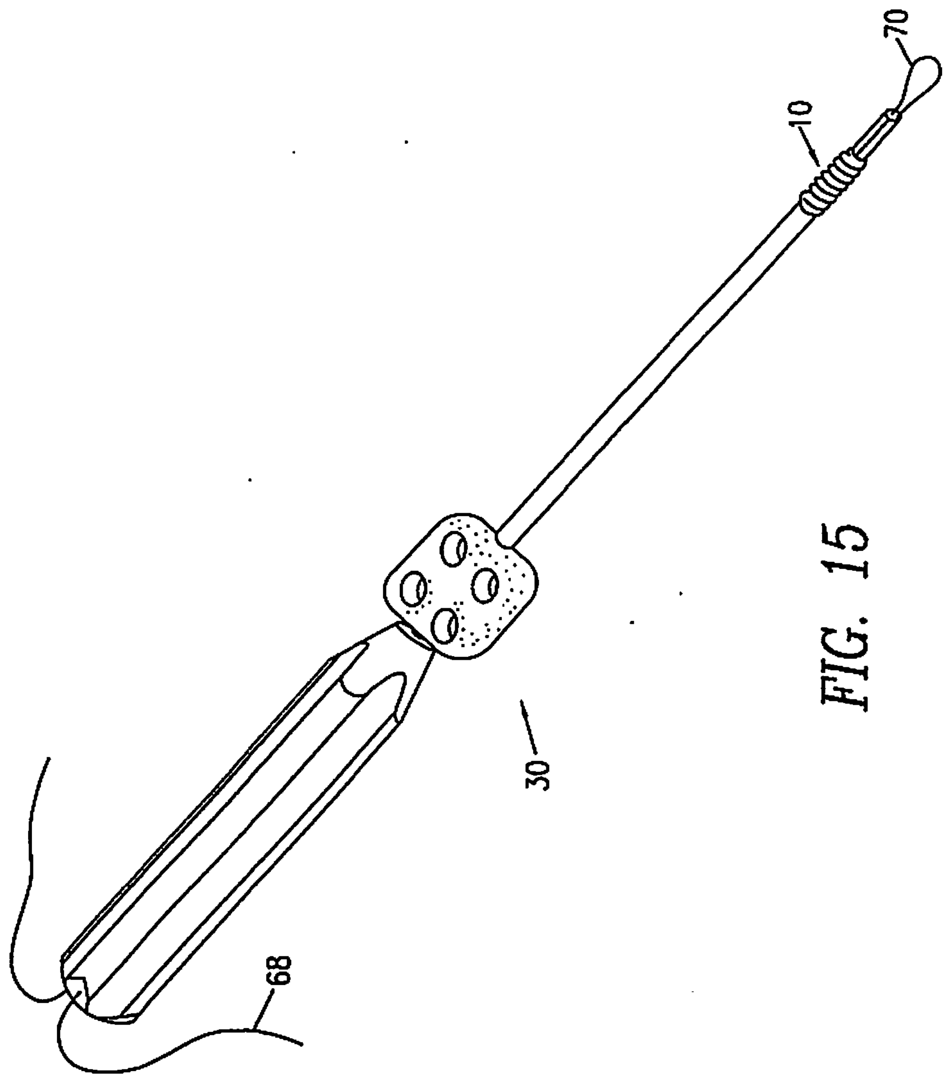

FIG. 15

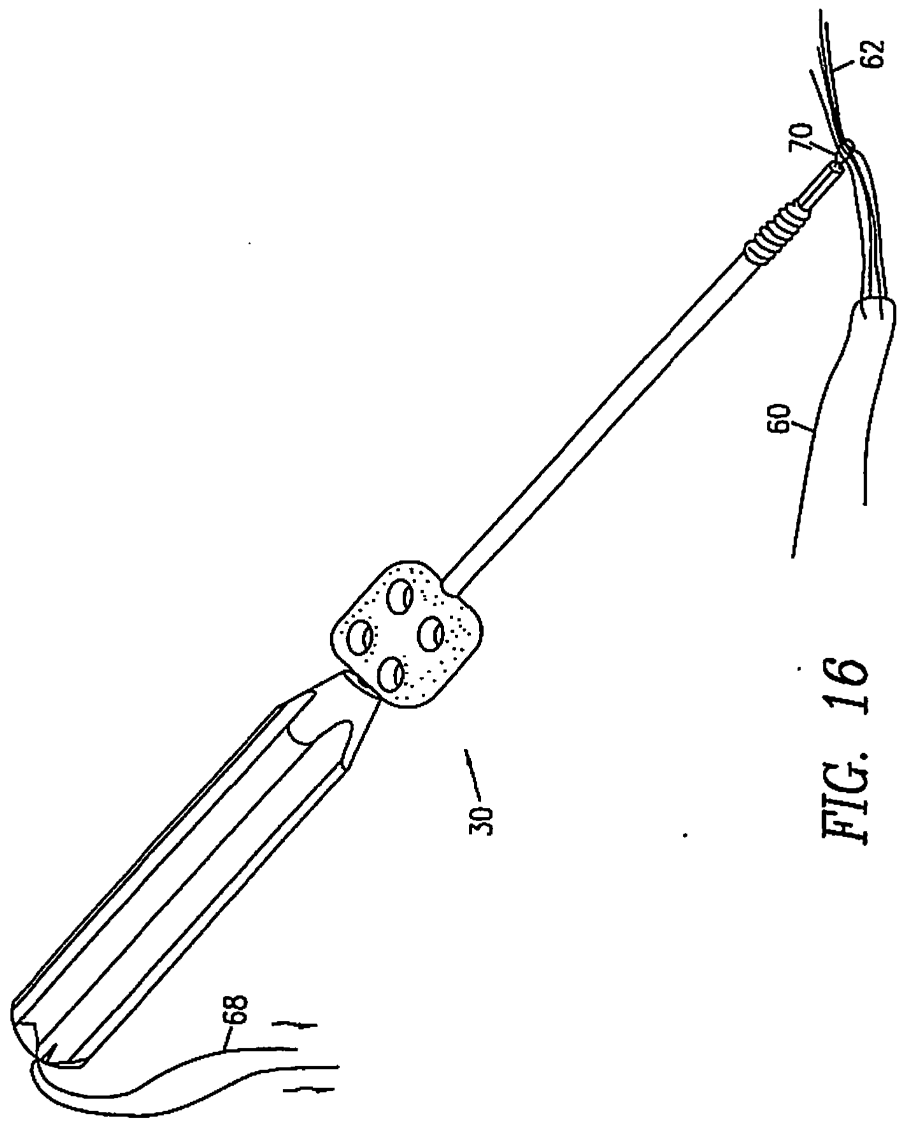

FIG. 16

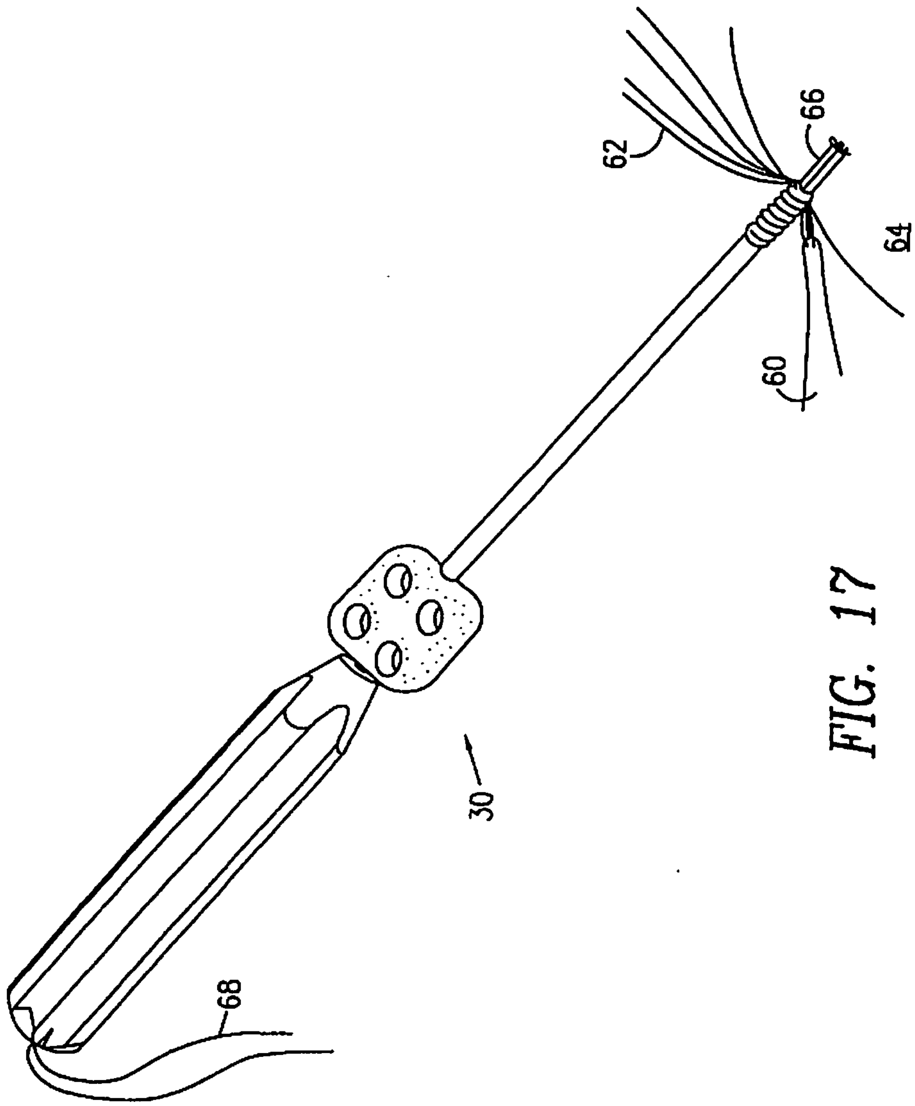

FIG. 17

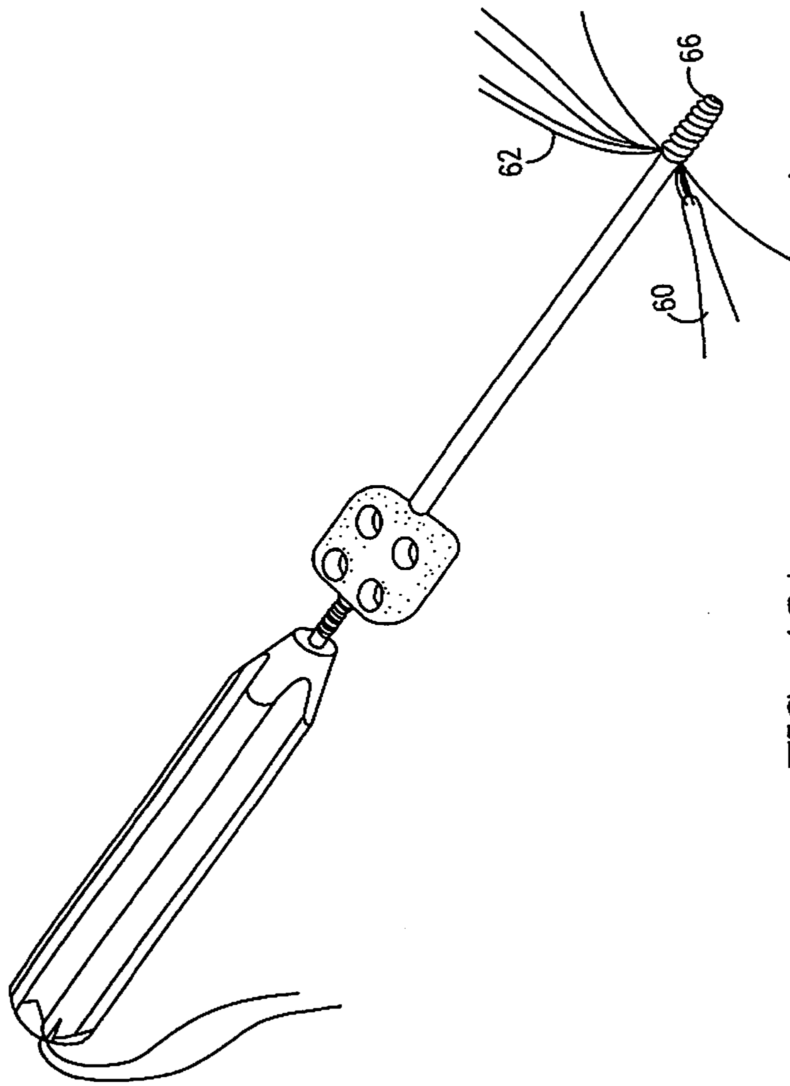

FIG. 18A

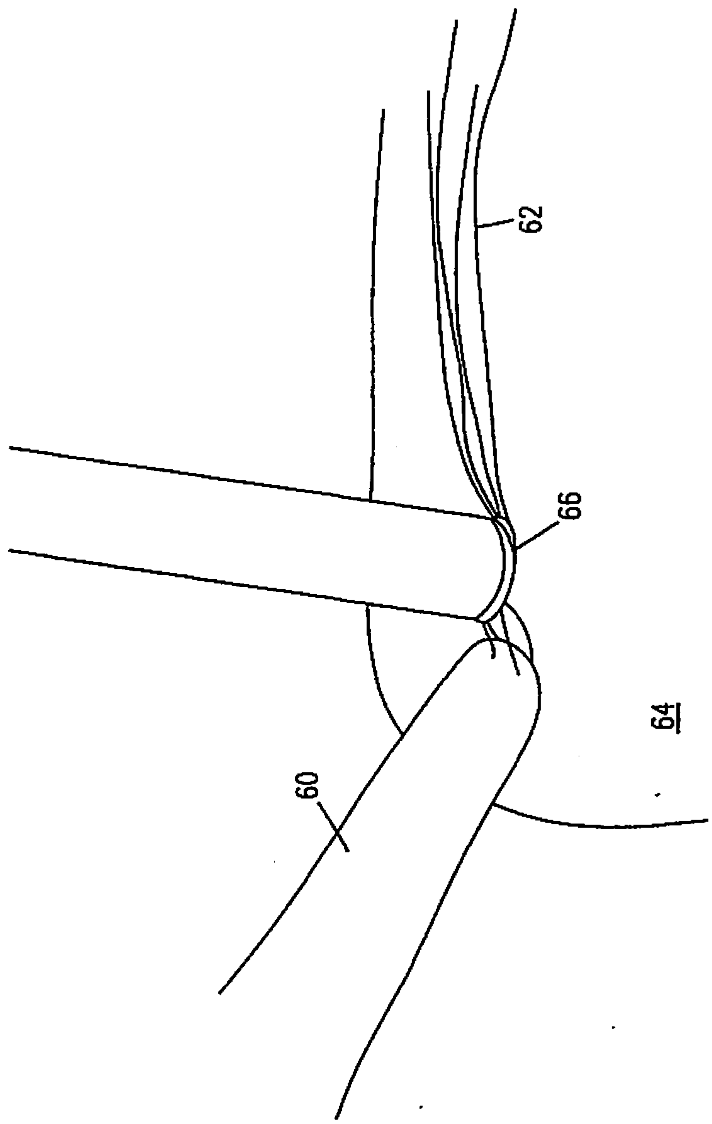

FIG. 18B

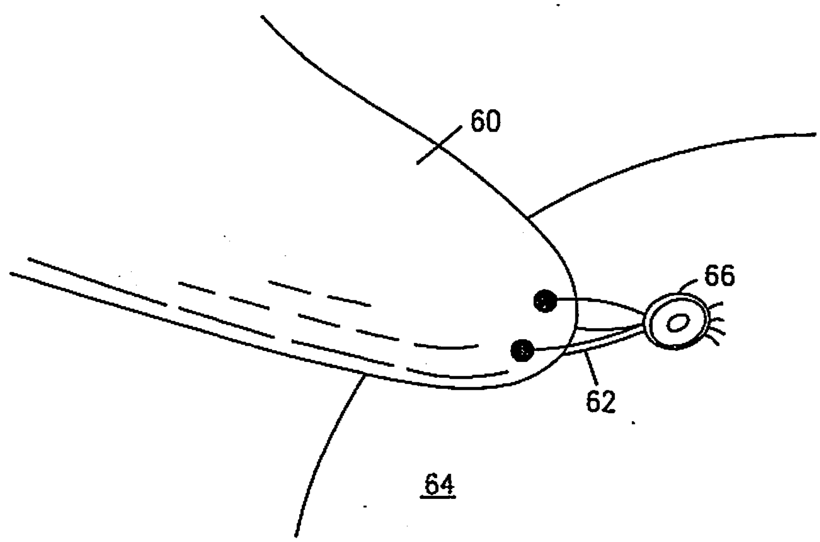

FIG. 19

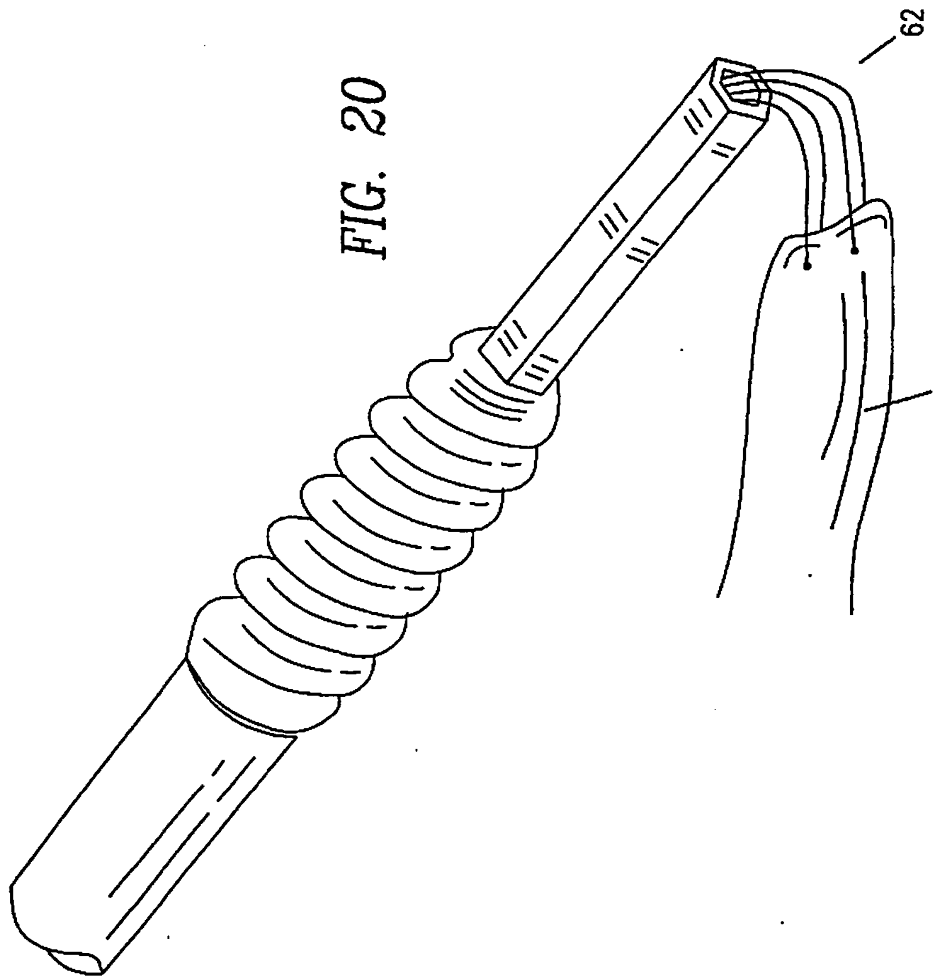

FIG. 20